(b) *Sponsor*. See 000061 in § 510.600(c) for 8-gram package, see 059320 for 1-gram package.

(c) *NAS/NRC status*. The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1 to 2 grams per 500 pounds of body weight, not to exceed 4 grams, daily, as required.

(ii) *Indications*. For the treatment of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Administer orally by adding to a portion of the usual grain ration. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Treated animals should not be slaughtered for food use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18960, Mar. 27, 1981, as amended at 46 FR 48642, Oct. 2, 1981; 57 FR 2836, Jan. 24, 1992; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 65 FR 20731, Apr. 18, 2000]

### § 520.1720c Phenylbutazone paste.

(a) *Specifications*—(1) Each gram of paste contains 0.2 grams phenylbutazone.

(2) Each gram of paste contains 0.35 grams phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) Nos. 000061 and 010797 for use of product described in paragraph (a)(1) of this section.

(2) No. 064847 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount*. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use*. For relief of inflammatory conditions associated with the musculoskeletal system.

(3) *Limitations*. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level of the lowest level capable of producing the desired clinical response. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 84762, Dec. 23, 1980, as amended at 58 FR 29777, May 24, 1993; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997; 68 FR 43926, July 25, 2003; 72 FR 60550, Oct. 25, 2007]

### § 520.1720d Phenylbutazone gel.

(a) *Specifications*. Each 30 grams of gel contains 4 grams of phenylbutazone.

(b) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(c) *NAS/NRC status*. The conditions of use are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Conditions of use in horses*—(1) *Amount*. 1 to 2 grams of phenylbutazone per 500 pounds of body weight, not to exceed 4 grams daily.

(2) *Indications for use*. For relief of inflammatory conditions associated with the musculoskeletal system of horses.

(3) *Limitations*. Use a relatively high dose for the first 48 hours, then gradually reduce to a maintenance level at the lowest level capable of producing the desired clinical response. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[50 FR 13561, Apr. 5, 1985, as amended at 50 FR 49372, Dec. 2, 1985; 55 FR 8462, Mar. 8, 1990; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

### § 520.1720e Phenylbutazone powder.

(a) *Specifications*—(1) Each 1.15 grams (g) of powder contains 1 g phenylbutazone.

(2) Each 10 g of powder contains 1 g phenylbutazone.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 027053 for use of product described in paragraph (a)(1) of this section.

(2) No. 057699 for use of product described in paragraph (a)(2) of this section.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 1 to 2 g (1 to 2 level scoops, using the scoop provided) per

500 pounds of body weight on a small amount of palatable feed, not exceed 4 g per animal daily.

(2) *Indications for use.* For the relief of inflammatory conditions associated with the musculosketetal system.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law prohibits the extralabel use of this product in female cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 27956, May 18, 2007]

### § 520.1780 Pimobendan.

(a) *Specifications.* Each chewable tablet contains 1.25, 2.5, or 5 milligrams (mg) pimobendan.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) *Indications for use.* For the management of the signs of mild, moderate, or severe (modified New York Heart Association Class II, III, or IV) congestive heart failure due to atrioventricular valvular insufficiency or dilated cardiomyopathy; for use with concurrent therapy for congestive heart failure as appropriate on a case-by-case basis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 27733, May 17, 2007]

### § 520.1802 Piperazine-carbon disulfide complex oral dosage forms.

### § 520.1802a Piperazine-carbon disulfide complex suspension.

(a) *Specifications.* Each fluid ounce of suspension contains 7.5 grams of piperazine-carbon disulfide complex. The piperazine-carbon disulfide complex contains equimolar parts of piperazine and carbon disulfide (1 gram contains 530 mgs of piperazine and 470 mgs of carbon disulfide).

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use. Horses and ponies*—(1) *Amount.* One fluid ounce per 100 pounds of body weight.[1]

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum)*, bots (*Gastrophilus* spp.), small strongyles, large strongyles (*Strongyles* spp.), and pinworms (*Oxyuris equi*).[1]

(3) *Limitations.* Administer by stomach tube or dose syringe after withholding feed overnight or for 8 to 10 hours. Provide water as usual. Resume regular feeding 4 to 6 hours after treatment. Treatment of debilitated or anemic animals is contraindicated. Do not administer to animals that are or were recently affected with colic, diarrhea, or infected with a serious infectious disease. As with most anthelmintics, drastic cathartics and other gastrointestinal irritants should not be administered in conjunction with this drug. Animals in poor condition or heavily parasitized should be given one half the recommended dose and treated again in 2 or 3 weeks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.[1]

[45 FR 52781, Aug. 8, 1980]

### § 520.1802b Piperazine-carbon disulfide complex boluses.

(a) *Specifications.* Each bolus contains 20 grams of piperazine-carbon disulfide complex.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use: Horses and ponies*—(1) *Amount.* For removal of ascarids and small strongyles, 1 bolus (20 grams) per 500 pounds body weight; removal of large strongyles, pinworms, and bots, 1 bolus per 250 pounds body weight.[1]

(2) *Indications for use.* For removing ascarids (large roundworms, *Parascaris equorum*), large strongyles (*Strongylus* spp.) bots (*Gastrophilus* spp.), small strongyles, and pinworms (*Oxyuris equi*).[1]

(3) *Limitations.* Withhold feed overnight or for 8 to 10 hours. Give water

[1] These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.